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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,263	02/11/2005	Takayuki Kanda	H6808.0075/P075	4131
24998 7590 10/17/2007 DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 10/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/524,263		KANDA ET AL.	
	Examiner		Art Unit	
	Christopher M. Babic		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/11/2005; 5/4/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claim(s) 1-5 and 11-14 in the reply filed on July 27, 2007 is acknowledged. The traversal is on the ground(s) that all claims can be searched without serious burden to the Examiner. This is not found persuasive because search burden is not a factor when determining whether inventions are linked as to form a single general inventive concept under PCT Rule 13.1. Applicant is reminded that the instant case is a national stage application submitted under 35 U.S.C. 371, wherein lack of unity rules under PCT 13.1, as opposed to U.S. restriction practices, are applied (see MPEP 1893.03(d), for example). The requirement is still deemed proper and is therefore made FINAL. Thus, claim(s) 6-10 and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Information Disclosure Statement

It is noted that only the English abstract of foreign patent JP 10-84999 has been considered, as an English translation of the patent document has not been provided. Furthermore, the Makino reference (marked CA on IDS dated 2/11/2005) has not been considered, as an English translation of the document has not been provided.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1-5 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim(s) 1-5 are indefinite for being incomplete for omitting essential steps. The omitted steps are: the active step of amplification of the target nucleic acid. The preamble of the claimed invention references --using-- a --mixture-- however, the claimed language does not recite an active method step of amplification. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See *Ex Parte Erlich*, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986).

(b) Claim(s) 11-14 are indefinite because claim 11 contains a broad limitation together with a narrowed limitation that falls within the said broad range. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). In the present instance, claim 11 recites the broad recitation --(A) a luminescent substance-labeled or modifying group-coupled oligomer A-- and the claim

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also recites --the step of coupling in which a luminescent substance is coupled to said modifying group when said oligomer A is a modifying group-coupled one--, which is a narrower statement of the range/limitation. In other words, it is unclear whether a modifying group-coupled oligomer A is required by the claimed invention. Furthermore, the narrower limitation renders the entire --coupling step-- indefinite because the step is dependent on the presence of the modifying group-coupled oligomer A.

(c) Claim(s) 11-14 are further indefinite because it is unclear whether the --detecting step-- is referencing the luminescent substance of limitation (A) or the luminescent substance of the --coupling step--. Furthermore, since it is unclear whether the --coupling step-- is required by the claimed invention, and it is unclear which luminescent substance is referenced within the --detecting step--, the entire --detecting step-- is indefinite because it is unclear whether the step itself is required by the claimed invention. Thus, the steps of coupling and detecting will be treated as optional with regard to the prior art (see rejections below).

Moreover, claim(s) 12-13 are indefinite because it is unclear whether the --detecting step-- is referencing the luminescent substance of limitation (A) or the luminescent substance of the --coupling step--. Thus, the step of operation will be treated as optional with regard to the prior art (see rejections below).

(d) Claim(s) 1-5 and 11-14 recite the limitation "said specific sequence" in limitation (B). There is insufficient antecedent basis for this limitation in the claim. Limitation (A) recites --an arbitrary specific sequence-- rather than a --specific sequence--. Furthermore, it is unclear how a sequence can be simultaneously --

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arbitrary-- and --specific--. Thus, oligomers A and B will be treated as capable of comprising the same or different sequences, as long as both oligomers are capable of hybridizing to the target sequence.

Furthermore, claim(s) 14 recites the limitation --the detection apparatus used in said detection step--. There is insufficient antecedent basis for this limitation in the claim. Thus, the limitation will be treated as encompassing any detectable concentration that can be measured.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1-5 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlberg et al. (U.S. 5,888,780).

With regard to claim(s) 1, Dahlberg teaches a method of asymmetric PCR (col. 81, lines 1-20, for example), which utilizes two differently labeled primers. Specifically, Dahlberg teaches a nucleic acid amplification method using a mixture containing a target nucleic acid (col. 81, lines 1-20, DNA substrate, for example), reagents for amplification (col. 81, lines 1-20, PCR reagents as in example 11 (col. 72, lines 15-30),

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for example), a luminescent substance-labeled oligomer capable of hybridizing to the target nucleic acid (col. 81, lines 1-20, fluorescein labeled primer, for example), and an oligomer not labeled with the same substance of the said luminescent labeled oligomer (col. 81, lines 1-20, biotin labeled primer, for example). It is noted that this rejection is made in part due to the indefiniteness of the oligomer description, as noted in the above indefiniteness rejection (see above USC 112 rejection). Oligomers A and B will be treated as capable of comprising the same or different sequences, as long as both oligomers are capable of hybridizing to the target sequence.

With regard to claim(s) 2 and 3, Dahlberg teaches a ratio of primers of 1:100 (col. 81, lines 1-20, 1:100 pmoles, for example).

With regard to claim(s) 4 and 5, Dahlberg teaches fluorescent and biotin labels (col. 81, lines 1-20, labeled primers, for example).

With regard to claim(s) 11-13, the steps of coupling and detecting will be treated as optional with regard to the prior art (see above USC 112 rejection). Thus, please refer to the rejection of claim 1 above as all the required limitations of claim 11 are taught by Dahlberg.

With regard to claim(s) 14, the limitation will be treated as encompassing any detectable concentration that can be measured (see above USC 112 rejection).

Dahlberg teaches fluorescers capable of being detected (col. 81, lines 1-20, fluorescein labeled primer, for example).

Conclusion

Claim(s) 1-5 and 11-14 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Patent Examiner

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/Young J. Kim/

Primary Examiner

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